

§ 71.37 Exemption of color additives for investigational use.

(a) A shipment or other delivery of a color additive or of a food, drug, or cosmetic containing such a color additive for investigational use by experts qualified to determine safety shall be exempt from the requirements of section 402(c), 501(a), or 601(e) of the act, provided that the color additive or the food, drug, or cosmetic containing the color additive bears a label which states prominently, "Caution—Contains new color additive—For investigational use only." No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Subpart A—Foods

Sec.

- 73.1 Diluents in color additive mixtures for food use exempt from certification.
73.30 Annatto extract.

- 73.35 Astaxanthin.
73.40 Dehydrated beets (beet powder).
73.50 Ultramarine blue.
73.75 Canthaxanthin.
73.85 Caramel.
73.90 β -Apo-8'-carotenal.
73.95 β -Carotene.
73.100 Cochineal extract; carmine.
73.140 Toasted partially defatted cooked cottonseed flour.
73.160 Ferrous gluconate.
73.165 Ferrous lactate.
73.169 Grape color extract.
73.170 Grape skin extract (enocianina).
73.185 Haematococcus algae meal.
73.200 Synthetic iron oxide.
73.250 Fruit juice.
73.260 Vegetable juice.
73.275 Dried algae meal.
73.295 Tagetes (Aztec marigold) meal and extract.
73.300 Carrot oil.
73.315 Corn endosperm oil.
73.340 Paprika.
73.345 Paprika oleoresin.
73.355 Phaffia yeast.
73.450 Riboflavin.
73.500 Saffron.
73.575 Titanium dioxide.
73.600 Turmeric.
73.615 Turmeric oleoresin.

Subpart B—Drugs

- 73.1001 Diluents in color additive mixtures for drug use exempt from certification.
73.1010 Alumina (dried aluminum hydroxide).
73.1015 Chromium-cobalt-aluminum oxide.
73.1025 Ferric ammonium citrate.
73.1030 Annatto extract.
73.1070 Calcium carbonate.
73.1075 Canthaxanthin.
73.1085 Caramel.
73.1095 β -Carotene.
73.1100 Cochineal extract; carmine.
73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
73.1150 Dihydroxyacetone.
73.1162 Bismuth oxychloride.
73.1200 Synthetic iron oxide.
73.1298 Ferric ammonium ferrocyanide.
73.1299 Ferric ferrocyanide.
73.1326 Chromium hydroxide green.
73.1327 Chromium oxide greens.
73.1329 Guanine.
73.1375 Pyrogallol.
73.1400 Pyrophyllite.
73.1410 Logwood extract.
73.1496 Mica.
73.1550 Talc.
73.1575 Titanium dioxide.
73.1645 Aluminum powder.
73.1646 Bronze powder.
73.1647 Copper powder.
73.1991 Zinc oxide.